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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/588,884

08/27/2007

Karl G. Csaky

NIHA 0383

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08/04/2010

OTT- NIH

c/o WOODCOCK WASHBURN LLP

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EXAMINER

AUDET, MAURY A

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

08/04/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/588,884	<b>Applicant(s)</b> CSAKY ET AL.	
	<b>Examiner</b> MAURY AUDET	<b>Art Unit</b> 1654	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 1-19 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20,21,23 and 25 is/are allowed.
- 6) ☒ Claim(s) 22 and 24 is/are rejected.
- 7) ☒ Claim(s) 26-29 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/23/10, 7/27/07, 7/19/07</u> .                               | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group III, claims 20-29, as drawn to the elected peptides of SEQ ID NOS: 1-5, in the reply filed on 4/30/10 is acknowledged. The traversal is on the ground(s) that the groups should be kept together under Rule 13.2. This is not found persuasive because, as provided in the restriction, Rule 13.2 permits a combination of a single product, single method of use ("an independent claim for ... a use", not more than one independent claim for more than one use), and a single method of making; but not more than one of any of the three. Here Applicant is claiming two entirely distinct methods of use: treating any condition associated with neovascularization v. treating any cancer.

The requirement is still deemed proper and is therefore made FINAL.

### ***Claim Objections***

Claims 26-29 are objected to because of the following informalities: the kits are drawn to both product subject matter and method of use subject matter (a different group that is withdrawn). The latter of which is not subject matter examined on the merits based on the election; the intended use of a product does not bear patentable weight on said product. Applicant is asked to consider amending the four kit claims into a single claim (cancelling the rest):

"26. (Currently Amended) A kit comprising (a) a composition comprising a peptide with an amino acid sequence selected from the group consisting of SEQ ID NO: 1-5 and (b) instructions for administration of said composition."

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[The methods of use may be rejoined and fully examined on the merits at a later time (under *In re Ochiai*), should Applicant so desire (and any intended use language found allowable as a method of use, reincorporate into the kits, if desired). ]

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112 2nd***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 22 and 24 the terms/phrase "modification" and "comprises one more D form amino acids" are indefinite. What modification? Where? Likewise, which amino acids are to be put into D amino form? In both cases, how and where can such modifications to be made, such that the utility of the peptide is maintained. The Examiner was unable to find a definition for each that answered the issues raised under indefiniteness.

Applicant may wish to consider cancelling claims 22 and 24, without prejudice.

### ***Allowable Subject Matter***

Claims 20-21, 23, and 25, as drawn to compositions comprising SEQ ID NOS: 1-5 were not found to be reasonably taught or suggested by the prior art of record, based on the ABSS sequence search of the relevant databases for SEQ ID NOS: 1-5.

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***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960.

The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 7/19/2010

/Maury Audet/  
Primary Examiner, Art Unit 1654